

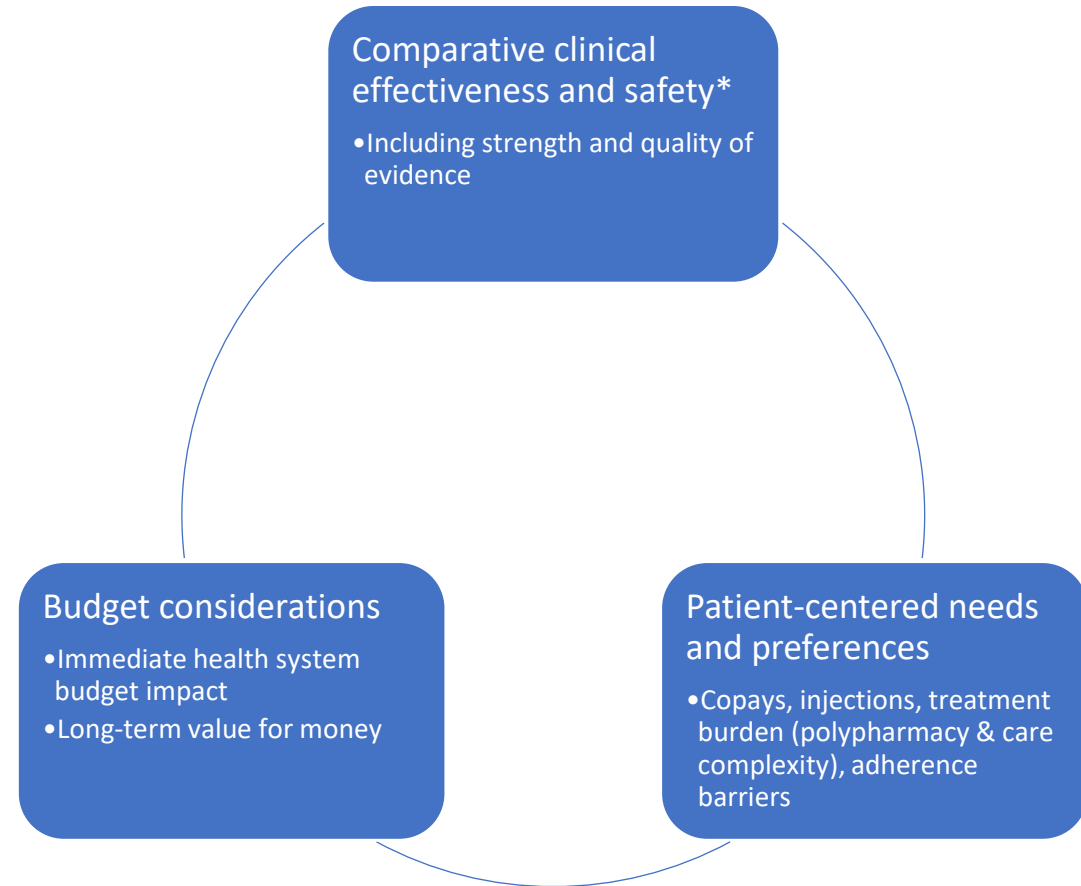
System P&T Processes to Promote Better Informed Decisions

Background

- P&T will be charged with making multiple high-impact decisions on formulary management
- Many decisions will require efficient evaluation of complex evidence
- Council members have limited time to thoroughly evaluate all evidence and other considerations in detail
- There is a need for decision aids that will enable P&T members to make informed decisions confidently and efficiently

Value Assessment Framework

- Decision to add/remove/restrict a medication is made based on multiple criteria which should be made explicit
- ICER's Value Assessment Framework provides a good baseline



* Comparative effectiveness is defined as evidence of outcome improvement versus standard-of-care under real-world treatment conditions

Burden of Proof

- Code of Federal Regulations regarding FDA approval process has important language regarding burden of proof

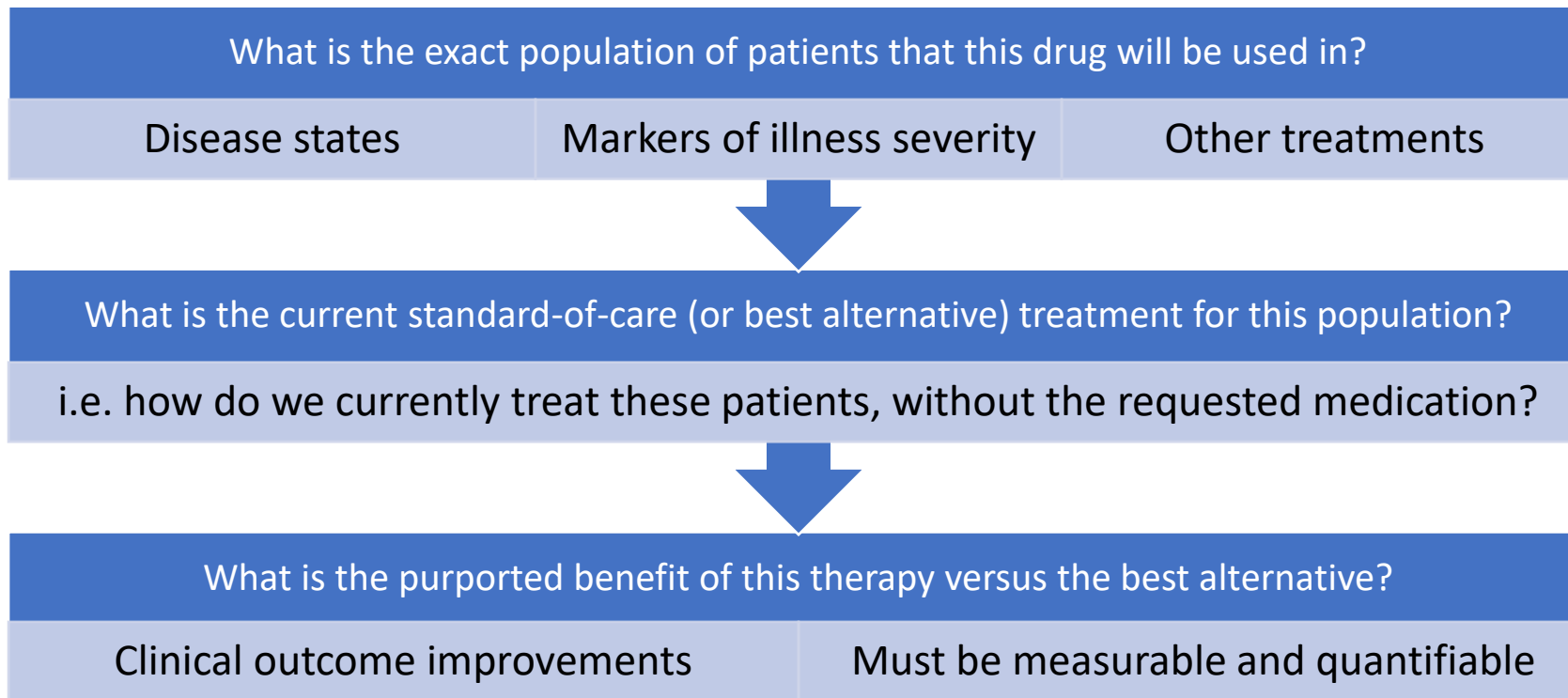
At a hearing involving issuing, amending, or revoking a regulation or order relating to the safety or effectiveness of a drug, device, food additive, or color additive, **the participant who is contending that the product is safe or effective or both and who is requesting approval or contesting withdrawal of approval has the burden of proof in establishing safety or effectiveness** or both and thus the right to approval. The burden of proof remains on that participant in an amendment or revocation proceeding.
[44 FR 22339, Apr. 13, 1979, as amended at 64 FR 399, Jan. 5, 1999]

- Our P&T can adopt similar language, example:

“The participant who is requesting formulary addition of a medication or contesting restriction/removal from formulary has the burden of proof in establishing safety and clinical effectiveness of the medication over best clinical alternative or existing standard-of-care treatment”

Structured Presentation of Requests

- Structured presentation of formulary requests will enable councils to evaluate evidence more efficiently



What is the exact population of patients that this drug will be used in?

Disease states

Markers of illness severity

Other treatments



What is the current standard-of-care (or best alternative) treatment for this population?

i.e. how do we currently treat these patients, without the requested medication?



What is the purported benefit of this therapy versus the best alternative?

Clinical outcome improvements

Must be measurable and quantifiable

Other Decision Aids

- “Devil’s advocate” approach
 - Identify an individual to present the best argument against using the drug
 - Ensures that decisionmakers are presented with a balanced discussion
- Benchmarking – what are other hospitals doing?
 - Premier QA benchmarking
 - Formulary status at other institutions
- CPRQ-Driven Learning Health System Evaluation
 - Provide additional evidence when benefit is uncertain
 - Re-evaluate decision in 6-12 months based on timely local evidence